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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|------------------------------------------------------------------------------------------------------|-----------------|----------------------|-------------------------|-----------------|
| 09/778,268 | 02/06/2001 | Joseph Gross | E1067/20025 | 5215 |
| 3000 7 | 7590 09/24/2003 | | | |
| CAESAR, RIVISE, BERNSTEIN, | | | EXAMINER | |
| COHEN & POKOTILOW, LTD. 12TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212 | | | COMPTON, ERIC B | |
| | | | ART UNIT | PAPER NUMBER |
| | • | | 3726 | 7 |
| | | | DATE MAILED: 09/24/2003 | X |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|----------------------------------------------------|--|--|--|--|
| Office Action Summers | 09/778,268 | GROSS ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Eric B. Compton | 3726 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address Peri d for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status | | | | | | |
| 1) Responsive to communication(s) filed on | <u>_</u> . | | | | | |
| 2a) ☐ This action is FINAL . 2b) ☑ This action is non-final. | | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims | | | | | | |
| 4) Claim(s) 16-18 and 25 is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>16-18 and 25</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Examiner. | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner. | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a)⊠ All b)□ Some * c)□ None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. ☑ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | |
| a) ☐ The translation of the foreign language provisional application has been received. 15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informal F | (PTO-413) Paper No(s) Patent Application (PTO-152) | | | | |
| U.S. Patent and Trademark Office PTOL-326 (Rev. 04-01) Office Ac | tion Summary | Part of Paper No. 8 | | | | |

Art Unit: 3726

DETAILED ACTION

Claim R j ctions - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 16-17 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2298368 to Cockburn in view of JP 63-207546 to Saito et al (SAITOU IKA KOGYO KK).

Cockburn discloses a needle (30, Figure 3) for delivery of a flowable material (see page 3, lines 13-15) having a shaft with an internal bore and an external surface including a side portion having an aperture (32A) in communication with the bore of the shaft (see claim 1). Cockburn discloses that the "aperture is formed by a transverse channel cut into the cylindrical wall of said needle." Claim 2.

However, Cockburn does not suggest arranging a plurality of shafts in a row parallel with one another and performing the shaft opening across the row of shafts.

Saito et al disclose a method of forming hypodermic needles (see Figure 6) comprising arranging a plurality of shafts (15) in a row parallel with one another and (see Figure 1) and running a grinding stone (12) across the row of shafts (15) to create an a traverse aperture (12a) across the plurality of shafts. Since, the shaft is to become a hypodermic needle it is inherent that a bore is to be formed within the shaft either before or after the after process, although not expressly disclosed.

Art Unit: 3726

Regarding claim 16, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have formed the needle of Cockburn by arranging a plurality of shafts in a row parallel with one another and performing the shaft opening across the row of shafts, in light of the teachings of Saito et al, in order to increase efficiency by grinding a plurality of shaft in one operations. JPO English Abstract of Saito et al.

Regarding claim 25, the shaft opening operations of both Cockburn and Saito et al can be considered a machining operation (i.e., material removing processes).

Regarding claim 17, Saito et al disclose the machining operation compriseds running a grinder across the row of shafts to grind a line of the apertures across the external surfaces of the shafts. Figures 1-5.

3. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cockburn/Saito et al as applied to claim 16 above, and further in view of U.S Patent 2,802,310 to Chaplik.

Cockburn/Saito et al disclose the invention cited above. Both references show an inclined tip on the needle. It is inherent that the tip of the needle is used to puncture or pierce through tissue, thus it inherently must be sharp. However, they do not disclose sharpening the needle while they are arranged parallel in a row.

Chaplik discloses a method and apparatus for grinding the tip of a hypodermic needle with a grinding wheel to sharpen it.

Regarding claim 18, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have sharpened the shafts of

Art Unit: 3726

Cockburn/Saito et al, while they were arranged in a row, in order to sharpen all of the tips of the needles to provide a clean slit with inserted into tissue. Chaplik, Col. 1, lines 39-44. Again, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have performed the sharpening process while the shafts are arrange parallel in a row in order to increase efficiency. JPO English Abstract of Saito et al.

Prior Art References

The prior art references listed on the enclosed PTO-892, but not used in a rejection of the claims, are cited for their teachings of forming needles.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric B. Compton whose telephone number is (703) 305-0240. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory M. Vidovich can be reached on (703) 308-1513. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

Art Unit: 3726

Eric Compton
Patent Examiner

A/U 3726

September 16, 2003

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